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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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TITLE OF THE INVENTION (500 characters max)

METHOD AND APPARATUS FOR AN IMPROVED FLUID SAMPLING DEVICE

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ENCLOSED APPLICATION PARTS (check all that apply)

☑ Specification *Number of Pages* 13
☑ Drawing(s) *Number of Sheets* 5
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☑ Other (specify) Application cover sheet; return postcard

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☑ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees
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Respectfully submitted,

SIGNATURE _____ Date 06/13/2003

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TELEPHONE (650) 324-7000 Docket Number: 38187-2686

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Docket Number	38187-2686

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Number 2 of 2

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PROVISIONAL PATENT APPLICATION

METHOD AND APPARATUS FOR AN IMPROVED FLUID SAMPLING DEVICE

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Attorney Docket No.: 38187-2686

METHOD AND APPARATUS FOR AN IMPROVED FLUID SAMPLING DEVICE

BACKGROUND OF THE INVENTION

Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet. Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major impediment to patient compliance with a structured glucose monitoring regime.

Another impediment to patient compliance is the lack of spontaneous blood flow generated by known lancing technology. In addition to the pain as discussed above, a patient may need more than one lancing event to obtain a blood sample since spontaneous blood generation is unreliable using known lancing technology. Thus the pain is multiplied by the number of attempts required by a patient to successfully generate spontaneous blood flow. Different skin thickness may yield different results in terms of pain perception, blood yield and success rate of obtaining blood between different users of the lancing device. Known devices poorly account for these skin thickness variations.

A still further impediment to improved compliance with glucose monitoring are the many steps and inconvenience associated with each lancing event. Many diabetic patients that are insulin dependent may need to self-test for blood glucose levels five to six times daily. The large number of steps required in traditional methods of glucose

testing, ranging from lancing, to milking of blood, applying blood to a test strip, and getting the measurements from the test strip, discourages many diabetic patients from testing their blood glucose levels as often as recommended. Older patients and those with deteriorating motor skills encounter difficulty loading lancets into launcher devices, transferring blood onto a test strip, or inserting thin test strips into slots on glucose measurement meters. Additionally, the wound channel left on the patient by known systems may also be of a size that discourages those who are active with their hands or who are worried about healing of those wound channels from testing their glucose levels.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved body fluid sampling device. Some embodiments of these penetrating member drivers, the invention relates to a new contact point algorithm that is run immediately before the actual lance event. At least some of these and other objectives described herein will be met by embodiments of the present invention.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving spontaneous blood generation. Some embodiments of the present invention provide an improved body fluid sampling device. For some embodiments of these penetrating member drivers, the invention relates to a new contact point algorithm that is run immediately before the actual lance event. At least some of these and other objectives described herein will be met by embodiments of the present invention.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the

like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

In one embodiment as seen in Figure 1, a body fluid sampling device 10 for use with a cartridge containing a plurality of penetrating members is provided. The device 10 comprises a penetrating member driver 12 (shown in phantom in Figure 3) for moving an active one of the penetrating members outward as indicated by arrow 14 from a first position outward to penetrate tissue. A housing 14 is coupled to the driver. A display 16 on the housing shows a number 18 of unused penetrating members remaining. The penetrating member driver is coupled to a position sensor, said sensor used to detect a position of the active one of said penetrating member.

In one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. As seen in Figures 1 through 4, the housing 14 may have a rectangular configuration.

In one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. The housing 14 may have a golden color. As seen in Figure 3, the position sensor 20 may be used to detect a position of the active one of said penetrating member.

Referring now to Figure 5, one embodiment of an improved fluid sampling device 100 is shown. The device 100 includes a display 102, a penetrating member actuation button 104, adjustment buttons 106 and 108, and a front end annular ring 110. In this embodiment, a slider 112 is movable as indicated by arrow 114. A pop-open button 116

is provided and is movable as indicated by 118. This opens the device 100 as shown in Figure 6. This embodiment of device 100 may also include a see-through window 120 that allows a user to see a cartridge inside the device 100. It should be understood that this window 120 may be provided in a variety of shapes including the U-shaped configuration shown in Figure 4, a full circular window, a U-shaped window on the top portion or mirror-imaged upward from the configuration shown in Figure 4, comprise of a plurality of smaller windows, or otherwise configured or positioned to show a user that a cartridge is inside the device. Referring now to Figure 5, the metallic quality of the housing 14 may be observed.

Referring now to Figure 6, in one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. A cavity 50 to house the cartridge 130 containing said penetrating members, said cartridge being a circular disc having a fracturable sterility seal covering a top opening and a side opening.

Referring now to Figure 6, the embodiment of device 100 is shown with the underside 140 hinged open. A battery 144 is shown in the compartment 142. The cartridge 130 is rotatable as indicated by arrow 146. It should be understood, of course, that the cartridge 130 may be designed to rotate in a counterclockwise direction in another embodiment. A rotatable gear 150 that is linked to slider 112, will rotate to rotate the cartridge 130. In the present embodiment, a support member 160 is provided to position the cartridge 130 in the areas where the penetrating member coupler 170 will engage the penetrating members. Although not limited to the following, the support member 160 is mounted on springs 162 which may allow the support to be moved downward and then urged back to its original position.

Referring now to Figure 7, in one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. The device allows for electronic setting of lancing parameters used by said penetrating member driver. A display 102 may be used to show the settings. Touch pads 180 and 182 may be used to receive input from buttons on the housing.

Referring now to Figure 7, in one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. Settings for lancing parameters used by said penetrating member driver remain in memory without battery. As a nonlimiting example, nonvolatile memory may be used to store the settings. As another nonlimiting example, an EEPROM may be used.

Referring now to Figure 8, in one embodiment, a body fluid sampling device 10 for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver 198 for moving an active one 200 of the penetrating members from a first position outward to penetrate tissue. A processor 202 having a safety feature such that the penetrating member driver only lances material with properties similar to skin. Thus as seen in Figure 8, if the penetrating member 200 in this embodiment fails to decelerate or indicate resistance consistent with that of flesh or skin, the processor 202 will abort the lancing event.

In one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. A processor 202 having a safety feature such that the penetrating member driver does not fire the active penetrating member in to air or materials harder than flesh. Thus if the penetrating member fails to sense resistance within a minimum distance such as about 100 microns, 75 microns, 50 microns, or other distance outward from the front end, then the controller will abort lancing event. Of course, other distances may be selected to be the stroke distance before the lancing event is aborted.

Referring now to Figure 9, in one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. A processor 202 may have a safety feature such that the penetrating member driver wherein a hard detect or an impact against material harder than tissue invalidates usage of the penetrating member 200. As seen in Figure 9, impact with a hard surface H may cause a spur 210 to form on the distal

tip of the penetrating member. Such a penetrating member with a spur 210 or bent tip should not be used.

In one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. A display showing penetrating members left/penetrating members spent. A display such as that in Figure 1 could adapted for such use.

In one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. Depth setting of penetrating member penetration into tissue independent of front end geometry. The device of Figure 1 could be adapted for such use with the buttons on it for adjustments.

In one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. The device may include a processor programmed to track position and energy used by the driver to sense position or proximity of skin. Similar to the scheme shown in Figure 8, if the penetrating member fails to engage tissue or material with tissue like resistance, lancing event is aborted.

In one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. A display that has a screen saver may be used with the device. The device of Figure 1 could be adapted for such use. As a nonlimiting example, the screensaver may be a small circle moving on the screen, a pattern being repeated on the display, or as other screen savers known to those of skill in the art.

In one embodiment, a body fluid sampling device for use with a cartridge containing a plurality of penetrating members is provided. The device comprises a penetrating member driver for moving an active one of the penetrating members from a first position outward to penetrate tissue. A display may be provided that relays a "too deep" signal to a user based on the lancing event. The device of Figure 1 could be

adapted for such use. Thus a processor 202 may determine that based on the resistance or other factors, the penetrating member went too deep. In some embodiments, this may also be based on whether the user indicated if blood was spontaneously generated, degree of pain felt, or other feedback. In other embodiments, the too deep indicator is based purely on tissue qualities detected by device and fed to the processor.

In one embodiment, the lancing device is the first fully-automated and integrated lancing system. Simply hold it up to the skin and press of a button. Instantly and painlessly a blood sample will appear. The device dramatically reduces the pain and inconvenience of other lancing systems. With a self-contained, sterile 50 lancet disk and fast, automatically controlled lancing a patient never needs to handle a new or used lancet again. They experience less pain and benefit from faster wound healing.

In one embodiment, the lancing device is based on the "one-step, one-button" approach. Simply hold the device up to the skin and press the button. Instantly, a painless blood sample will appear. (One can milk if more blood is needed.)

The lancing device incorporates a self-contained lancing disk that eliminates the need to load and discard lancets. The 50-lancet disk simply needs to be replaced after 50 uses.

As the first and only fully automated, self-contained lancing device, in one embodiment, the lancing device offers advantages over other lancing systems in 5 main areas: Pain, Convenience, Safety, Wound Healing, and Reliability.

1. Pain: Smart Lancing technology allows for fast, yet smooth electronically controlled lancing. Additionally, the lancing device is able to assess an individual's skin composition and only lance to lowest possible depth necessary to obtain an adequate sample.

2. & 3. Convenience and Safety: The device is completely self-contained and electronically controlled. The device only requires a user to press a single button to execute the entire lancing process. The device incorporates a self-contained, sterile 50-lancet disk so individuals with diabetes, most importantly children, will never see or handle a new or used lancet ever again.

4. Wound Healing: The fast, yet smooth electronically controlled lancing allows for minimal tissue damage and faster wound healing.

5. Reliability: The device eliminates the need for repetitive lancing due to insufficient blood samples. The lancing device results in an adequate blood sample nearly every single time.

We recommend using the disk to completion. In one embodiment, however, a partially used Disk can be used. Once re-inserted the number of lancets remaining will be displayed on the screen and the device will be ready for use.

In one embodiment, the lancing device is designed for the more convenient and physiologically accurate fingertip testing. Because the lancing device offers dramatically reduced pain and faster wound healing, AST is no longer necessary for patients.

The lancing device is designed for use by all individuals with diabetes and will be marketed to all individuals with diabetes who test their blood glucose levels. However, the lancing device is especially beneficial to children, who have sensitive skin and benefit the most from integrated convenience, safety, reduced pain, and faster wound healing.

In one embodiment, the product is a "one-step, one button" fully integrated blood glucose sampling and measurement solution. This product combines the sample acquisition benefits of the lancing device with superior measurement technology in one convenient device that will significantly reduce pain, eliminate daily medical waste, and provide superior monitoring reliability.

Like the lancing device, the second-generation glucose sampling and measurement device is completely self-contained and fully automated. This will allow a patient to execute the entire sample acquisition and measurement process by pressing one button. Patients will no longer need to have separate lancing devices and glucose meters. This product will be the only device that individuals with diabetes will need for glucose monitoring activities.

In addition to the reduced pain, increased convenience and enhanced reliability of the lancing device, this second-generation device also incorporates a replaceable combined test-strip/ lancet disk that eliminates the need for patients to load and discard lancets or test strips.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above embodiments, the location of the penetrating member

drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). With any of the above embodiments, the penetrating members may be a bare penetrating member during launch. With any of the above embodiments, the penetrating members may be bare penetrating members prior to launch as this may allow for significantly tighter densities of penetrating members. In some embodiments, the penetrating members may be bent, curved, textured, shaped, or otherwise treated at a proximal end or area to facilitate handling by an actuator. The penetrating member may be configured to have a notch or groove to facilitate coupling to a gripper. The notch or groove may be formed along an elongate portion of the penetrating member. With any of the above embodiments, the cavity may be on the bottom or the top of the cartridge, with the gripper on the other side. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The driver may use a through hole or other opening to engage a proximal end of a penetrating member to actuate the penetrating member along a path into and out of the tissue.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a housing coupled to said driver;

a display on said housing showing a number of unused penetrating members remaining.

2. The device of claim 1 wherein the penetrating member driver is coupled to a position sensor, said sensor used to detect a position of the active one of said penetrating member.

3. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a housing having a rectangular configuration.

4. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a housing having a golden color;

a position sensor, said sensor used to detect a position of the active one of said penetrating member.

5. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a cavity to house the cartridge containing said penetrating members, said cartridge being a circular disc having a fracturable sterility seal covering a top opening and a side opening.

6. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

electronic setting of lancing parameters used by said penetrating member driver.

7. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

settings for lancing parameters used by said penetrating member driver remain in memory without battery.

8. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a processor having a safety feature such that the penetrating member driver only lances material with properties similar to skin.

9. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a processor having a safety feature such that the penetrating member driver does not fire the active penetrating member in to air or materials harder than flesh.

10. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a processor having a safety feature such that the penetrating member driver wherein a hard detect or an impact against material harder than tissue invalidates usage of the penetrating member.

11. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a display showing penetrating members left/penetrating members spent.

12. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

depth setting of penetrating member penetration into tissue independent of front end geometry.

13. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a processor programmed to track position and energy used by the driver to sense position or proximity of skin.

14. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a display that has a screen saver.

15. A body fluid sampling device for use with a cartridge containing a plurality of penetrating members comprising:

a penetrating member driver for moving an active one of said penetrating members from a first position outward to penetrate tissue;

a display that relays a "too deep" signal to a user based on the lancing event.

Fig. 1

Fig. 3

Fig. 2

Fig. 4

PELIKAN ● TECHNOLOGIES

Pelikan form factor

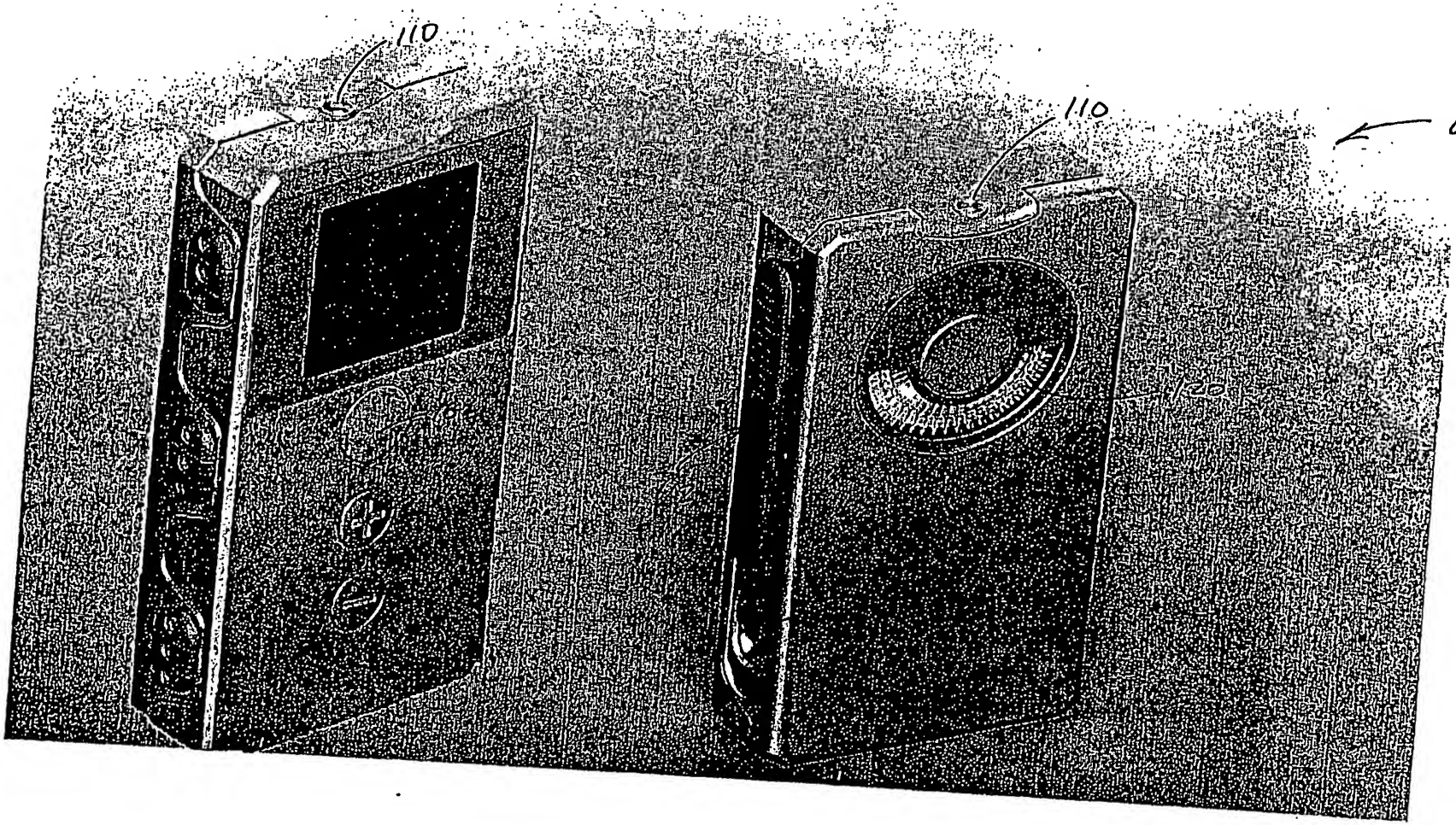

Figure 5

Figure 6

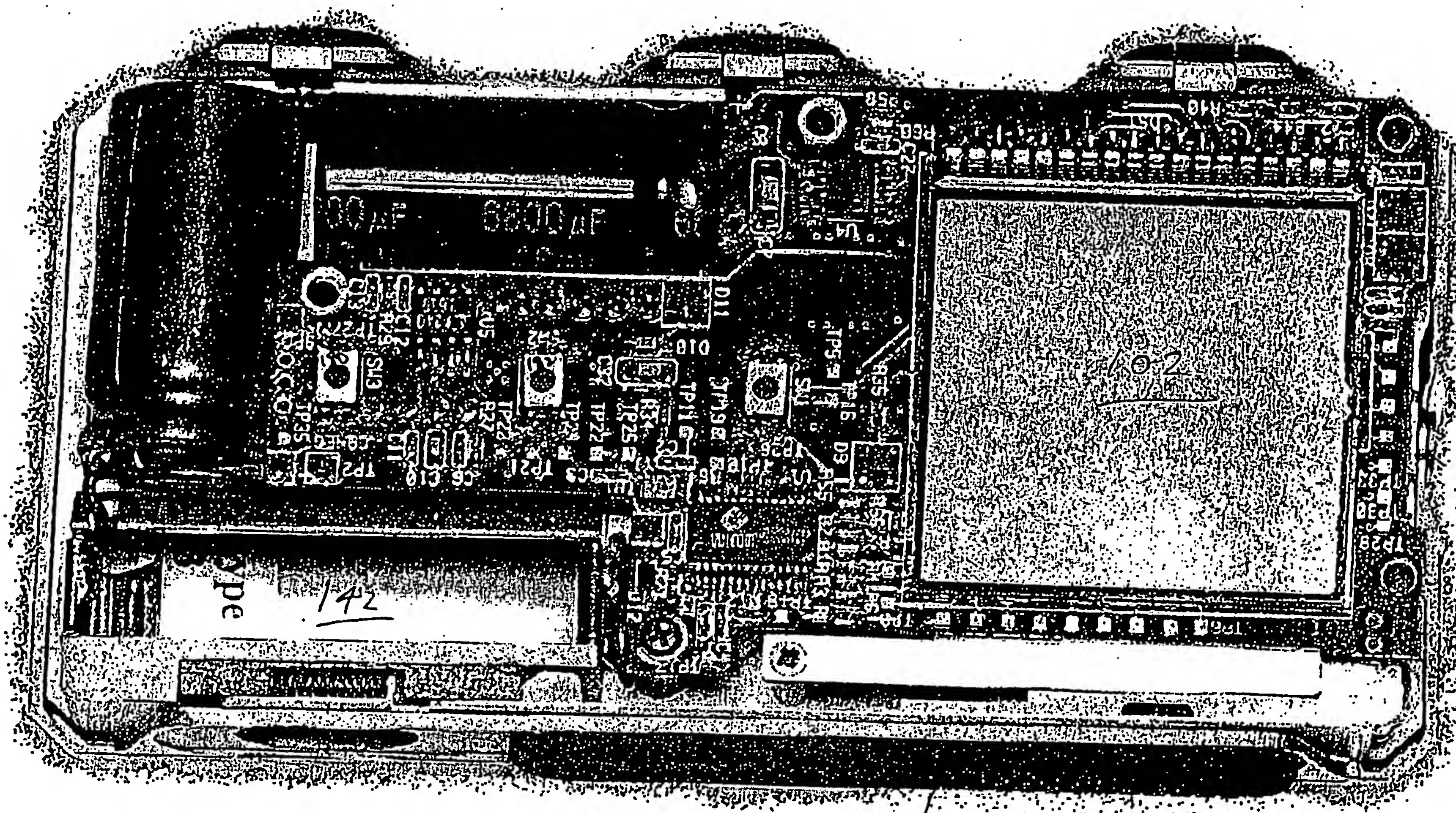

Figure 7

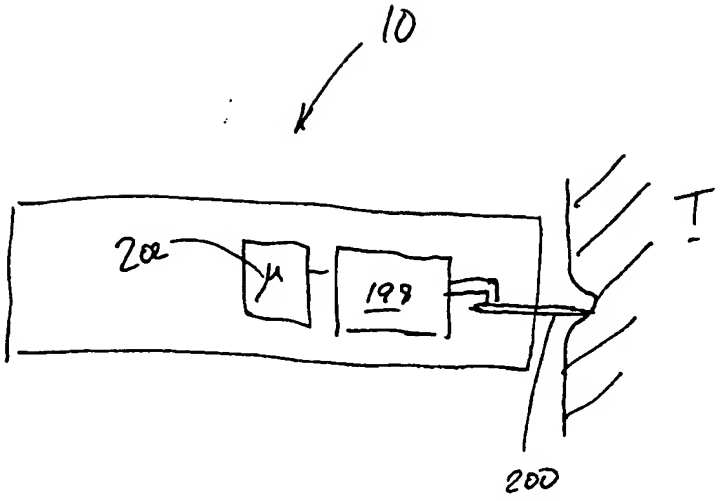

FIG_8

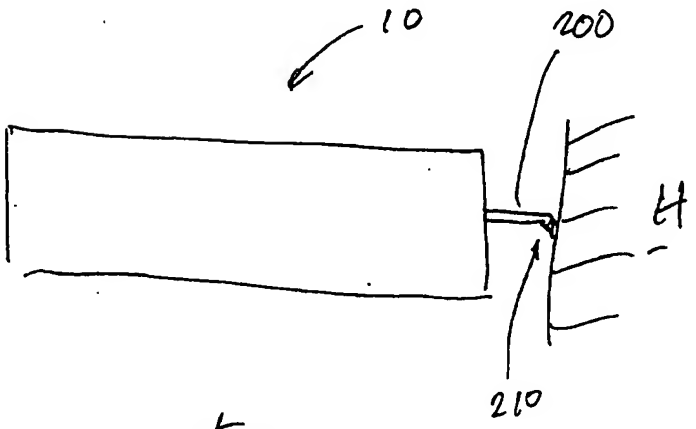

FIG_9